(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 November 2004 (25.11.2004)

PCT

(10) International Publication Number
WO 2004/100841 A1

(51) International Patent Classification[7]: A61F 2/44

(21) International Application Number:
PCT/US2004/014346

(22) International Filing Date: 7 May 2004 (07.05.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/431,648	7 May 2003 (07.05.2003)	US
10/431,650	7 May 2003 (07.05.2003)	US
10/430,902	7 May 2003 (07.05.2003)	US
10/431,633	7 May 2003 (07.05.2003)	US

(71) Applicant (*for all designated States except US*): **INTRINSIC THERAPEUTICS, INC.** [US/US]; 30 Commerce Way, Woburn, MA 01801 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **LAMBRECHT, Gregory, H.** [US/US]; 220 Eliot Street, Natick, MA 01760 (US). **KAVANAUGH, Sean** [US/US]; Hatties Way, Eastham, MA 02642 (US). **EINHORN, Jacob** [US/US]; 55 Verndale Street, Brookline, MA 02446 (US).

(74) Agent: **ALTMAN, Daniel, E.**; 2040 Main Street, Fourteenth Floor, Irvine, CA 92614 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

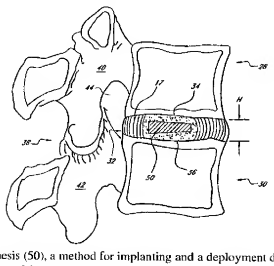
Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICES AND METHOD FOR AUGMENTING A VERTEBRAL DISC NUCLEUS



(57) Abstract: A vertebral disc prosthesis (50), a method for implanting and a deployment device (80) is provided. The prosthesis (50) is for deployment within the interior of the vertebral disc for restoring the functionality of the disc (e.g., the ability of the disc to transfer nutrients or otherwise survive, the ability of the disc to carry the required loads and absorb stress or the reduction of pain). The prosthesis (50) may be made of a material having a compression strength less than about 4 mn/m^2 and may include a grouping of multiple components that can be deployed as group.

WO 2004/100841 A1

another embodiment, a prosthesis for implantation into an interior region of a vertebral disc is provided. The vertebral disc includes first and second endplates. The prosthesis includes a mass of material that is adapted for insertion into the interior region of the vertebral disc so as to displace existing vertebral tissue. The mass of material is sized so as to be spaced from both the first and second endplates when implanted into the interior region of the vertebral disc such that the mass of material is surrounded with nucleus pulposus within the interior region of the vertebral disc when implanted therein.

In yet another embodiment, a prosthesis for implantation into an interior region of a vertebral disc is provided. The prosthesis includes an isotropic mass of biocompatible hydrogel having a compressive strength of less than about 4 MN/in^2 and a volume between a range of approximately 0.1 ml and approximately 6.0 ml.

In one embodiment, a prosthesis, or device, for implantation into a vertebral disc is provided. In one embodiment, the prosthesis comprises an isotropic mass of biocompatible hydrogel. In one embodiment, the biocompatible hydrogel has a compressive strength, a volume, and a mass. In one embodiment, the hydrogel has a compressive strength that is less than about 4 MN/m^2. In one embodiment, the volume is in the range of between about 0.1 ml and about 6.0 ml. In one embodiment, the mass of the hydrogel is adapted to absorb a volume of about 50% to about 100% of the volume of the hydrogel under a compressive stress between a range of about 0.2 MN/m^2 and about 0.8 MN/m^2. In one embodiment, the hydrogel absorbs a volume of about 50% to about 100% of its volume in about1 hour to about 8 hours.

In one embodiment, a vertebral disc prosthesis for displacing nucleus, annulus, or vertebral body endplate tissue of a vertebral disc is provided. In one embodiment, the prosthesis comprises a grouping of at least two discrete components. In one embodiment, the grouping is constructed and configured to be inserted together as a group into the interior region of a vertebral disc to displace at least a portion of the nucleus, annulus, or vertebral body endplate tissue. In one embodiment, a discectomy is not performed prior to the insertion of the components. In one embodiment, at least one of the components is used to displace tissue, and to replace tissue. In one embodiment, only displacement, and no replacement of tissue, occurs.

through an opening of the disc at the access site, an amount of prosthesis material into an interior region of the vertebral disc without removing a substantial amount of nucleus pulposus from the interior region so as to augment existing nucleus pulposus. The method also includes monitoring the intradiscal pressure to determine whether a desired intradiscal pressure is achieved.

In still another embodiment, a device for delivering a prosthesis material to an interior region of a vertebral disc is provided. The device includes a body having a proximal end and a distal end and a holder region disposed adjacent the distal end of the body. The holder region being adapted to hold the prosthesis material prior to delivery into the interior region of the vertebral disc. The device further includes a plunger disposed within the body. The plunger and body are adapted to move relative to each other to dispense the prosthesis material. A stop is disposed on the body. The stop is adapted to allow positioning of the body relative to the interior region of the vertebral body such that the prosthesis material can be dispensed within the interior region of the vertebral body at a desired location.

In yet another embodiment, a device for delivering a prosthesis to a site within an intervertebral disc is provided. In one embodiment, the delivery device has a body having a proximal end and distal end, the body being formed as a sleeve, which, in one embodiment, is at least partially hollow; a holder region disposed adjacent the distal end of the body, the holder being adapted to hold the prosthesis prior to delivery; and a plunger axially disposed within the sleeve. In one embodiment, the sleeve is adapted to be retracted relative to the plunger to dislodge the prosthesis from the holder region upon retraction of the sleeve.

In another embodiment, a device for delivering a prosthesis material to an interior region of a vertebral disc is disclosed. The device includes a body having a proximal end and a flexible distal end. The body defines a longitudinal axis. The flexible distal end is adapted to articulate relative to the axis. A holder region is disposed adjacent the distal end of the body. The holder region is adapted to hold the prosthesis material prior to delivery into the interior region of the vertebral disc. A plunger is disposed within the body. The plunger and body are adapted to move relative to each other to dispense the prosthesis.

with the prosthesis material, advancing at least a portion of the device to a desired location within the vertebral disc, and moving the plunger relative to the body to dislodge the prosthesis material from the device.

In still another embodiment, a kit of parts for use in augmenting vertebral tissue is disclosed. The kit includes a prosthesis according to any of the embodiments described herein; and a device for inserting the prosthesis into the interior region of the vertebral disc.

In yet another embodiment, a kit of parts for use in augmenting vertebral tissue is disclosed, the kit includes a prosthesis adapted for insertion into the vertebral disc; a delivery device for inserting the prosthesis into the interior region of the vertebral disc; and instructions for inserting the prosthesis, the instructions comprising instructions for inserting the prosthesis material into an interior region of the vertebral disc without removing a substantial amount of nucleus pulposus from the disc.

In still another embodiment, a kit of parts for use in augmenting vertebral tissue is disclosed. The kit includes a prosthesis adapted for insertion into the vertebral disc; a delivery device for inserting the prosthesis into the interior region of the vertebral disc; and instructions for inserting the prosthesis. The instructions comprising the any of the methods disclosed herein.

In still another embodiment, a kit of parts for use in augmenting vertebral tissue is disclosed. The kit includes a prosthesis adapted for insertion into the vertebral disc; and a delivery device according to any of the embodiments described herein.

In another embodiment, a vertebral disc prosthesis for displacing nucleus, annulus, or vertebral body endplate tissue of a vertebral disc is disclosed. The prosthesis includes a grouping of at least two discrete components. The grouping is constructed and configured to be inserted together as a group into the interior region of a vertebral disc to displace at least a portion of the nucleus, annulus, or vertebral body endplate tissue.

In yet another embodiment, a method of restoring function of an vertebral disc is disclosed. The vertebral disc has vertebral disc tissue comprising a nucleus, an annulus, and

FIG. 4 is a cross-sectional view of a portion of a functional spine unit, wherein a prosthesis according to still another aspect of the invention is shown;

FIG. 5 is a cross-sectional view of a portion of a functional spine unit, wherein a prosthesis according to yet another aspect of the invention is shown;

FIGS. 6A and 6B are views of a portion of a functional spine unit, wherein a prosthesis according to yet another aspect of the invention is shown;

FIGS. 7A and 7B are views of a functional spine unit, wherein a prosthesis according to yet another aspect of the invention is shown;

FIG. 8 is a cross-sectional view of a portion of a functional spine unit, wherein a prosthesis according to still another aspect of the invention is shown;

FIG. 9 is a cross-sectional view of a portion of a functional spine unit, wherein a prosthesis according to still another aspect of the invention is shown;

FIG. 10 is a cross-sectional view of a portion of a functional spine unit showing the prosthesis cooperating with a barrier according to another aspect of the invention;

FIG. 11 is diagrammatic representation of the vertebral disc showing a barrier positioned within the interior region of the disc;

FIGS. 12A through 12C are cross-sectional representations of a deployment device used to deploy the prosthesis according to one aspect of the invention;

FIG. 13 is an alternative embodiment of the deployment device shown in FIGS. 12A-12C;

FIGS. 14A-14D show alternative embodiments of a portion of the deployment device encircled by line 14 of FIG. 12A;

Loss of vertebral disc tissue, such as NP, deflates the disc, causing a decrease in disc height. Significant decreases in disc height have been noted in up to 98% of operated patients. Loss of disc height increases loading on the facet joints, which may result in deterioration of facet cartilage and ultimately osteoarthritis and pain. As the joint space decreases, the neural foramina formed by the inferior and superior vertebral pedicles also close down which could lead to foraminal stenosis, pinching of the traversing nerve root, and recurring radicular pain. Loss of NP also increases loading on the remaining AF, and can produce pain. Finally, loss of NP results in greater bulging of the AF under load, which may result in renewed impingement by the AF on nerve structures posterior to the disc. Removal of NP may also be detrimental to the clinical outcome of disc repair.

Applicants own, *inter alia*, U.S. Pat. Nos. 6,425,919; 6,482,235; 6,508,839 and Published U.S. Patent Application Ser. No. 2002/0151979, each of which is hereby incorporated by reference in its entirety, and discloses, *inter alia*, methods and devices directed to reinforcing and augmenting the annulus of an vertebral disc. As will be explained, such devices and methods can be used with the embodiments described herein.

In various aspects of the invention, a vertebral disc prosthesis, a method of implanting a prosthesis and a deployment device are disclosed.

In one aspect of the invention, the prosthesis is implanted into the interior region of the vertebral disc to move or displace, but not replace, the autologous or existing NP, AF or one or both endplates. The tissues of the AF, NP or endplate(s) is therefore displaced relative to the amount of prosthesis added. While a deminimis amount of vertebral tissue may be removed, a substantial amount of material (such as the NP) is not removed. In this manner, as will be explained, a more natural biomechanical state is achieved and functionality of the disc is retained. Prior methods include removal of some of the vertebral tissue, such as a substantial amount or all of the NP, which may disrupt the biomechanical function of the disc as well as the ability of the disc to survive. According to aspects of the present invention, the size or amount of prosthesis inserted into the interior region of the vertebral disc is a function of certain characteristics of the disc or the prosthesis. For example, the amount or size of prosthesis inserted into the disc may be dependent upon

opening and therefore reduce the likelihood that the prosthesis may be dispensed or extruded therefrom. Surgical approaches including transpsoas, presacral, transsacral, tranpedicular, translaminar, or anteriorly through the abdomen, may be used. The access opening can be located anywhere along the surface of the AF or even through the vertebral endplates.

Turning now to the figures, illustrative embodiments of the prosthesis and deployment device, and illustrative methods for inserting the prosthesis will now be described. Although certain features will be described with reference to a specific embodiment, the present invention is not limited in this respect, as any of the features described herein, and other suitable features, may be employed singularly or any suitable combination to form any suitable embodiment.

A functional spine unit includes the bony structures of two adjacent vertebrae (or vertebral bodies), the soft tissue (annulus fibrosis (AF), nucleus pulposus (NP), and endplates) of the vertebral disc, and the ligaments, musculature and connective tissue connected to the vertebrae. The vertebral disc is substantially situated in the vertebral space formed between the adjacent vertebrae.

FIGS. 1A and 1B show the general anatomy of a functional spine unit **10**. As used herein, the terms 'anterior' and 'posterior', 'superior' and 'inferior' are defined by their standard usage in anatomy, i.e., anterior is a direction toward the front (ventral) side of the body or organ, posterior is a direction toward the back (dorsal) side of the body or organ; superior is upward (toward the head) and inferior is lower (toward the feet).

FIG. 1A is a cross-sectional view of a vertebral body with the vertebral disc **15** superior to the vertebral body. Anterior (A) and posterior (P) sides of the functional spine unit are also shown. The vertebral disc **15** contains an annulus fibrosis (AF) **17** surrounding a central nucleus pulposus (NP) **20**. Also shown in this figure are the left **22** and right **22'** transverse spinous processes and the posterior spinous process **24**.

FIG. 1B is a side view of two adjacent vertebral bodies **28** (superior) and **30** (inferior). Vertebral disc space **32** is formed between the two vertebral bodies and contains vertebral

inserted into the disc **15** is a function of the desired height (H) of the disc **15**. As explained above, restoring disc height may be beneficial in reducing pain.

As will become clear hereinafter, it is to be appreciated that the prosthesis or prosthesis material implanted into the interior region of the vertebral disc may have a predetermined geometry or may be initially in bulk form allowing a surgeon or other technician to insert a desired amount of the prosthesis or prosthesis material into the interior region of the disc. Thus, in embodiments where the prosthesis or prosthesis material is of a pre-formed geometry, the tern "prosthesis" may be used. In embodiments where the prosthesis or prosthesis material is a portion of a bulk material (such as when the prosthesis or prosthesis material is formed from a liquid or fluid material) the phrase "prosthesis material" may be used. In both embodiments, however, reference numeral "50" is used. Nevertheless, the present invention is not limited in this respect, as the term "prosthesis" may be used to refer to a portion of a bulk material and the term "prosthesis material" may be used to refer to a pre-formed geometry. As such, the term "prosthesis" is used herein to generically refer to either embodiment.

Determining the height (H) may be performed using any suitable means or method, as the present invention is not limited in this respect. In one embodiment, a caliper or other measuring device to determine the disc height may be used. Alternatively, disc height may be monitored using any suitable imaging system, such as MRI, X-ray or CT Scan, as the present invention is not limited in this respect. Further, such height data may be obtained either during the procedure or post-operatively by, for example, comparing pre- and post-operative disc heights. Once the desired disc height (H) is achieved, continued insertion of the prosthesis **50** into the interior region is terminated. The desired disc height (H) may be determined on a case by case basis. In one embodiment, the disc height (H) may be increased by an amount ranging between approximately 1 mm and approximately 10 mm. Other suitable ranges include 0.1 mm-5 mm and 5 mm-10 mm or even a narrower range, such as 0.1 mm-3 mm, 3 mm-6 mm and 6 mm-9 mm. It should be appreciated that embodiments of the present invention are not limited to any particular resulting disc height (H), as other final disc heights or ranges may be desired.

According to one aspect of the invention, increasing disc pressure may be desirable to

52 may be measured directly by monitoring the amount or size of the prosthesis itself. It should be appreciated that embodiments of the present invention are not limited in this respect, as other suitable methods of monitoring disc or prosthesis volume may be employed. The volume of the prosthesis material may also be adjusted to compensate for extra swelling due to, for example, any existing herniations in the AF 17. For example, the volume of the prosthesis material 50 inserted into the interior region 52 may be increased to accommodate such swelling.

A direct measurement of the amount of prosthesis material being inserted may be employed, such as by the use of a metered dispensing implement. Alternatively, because the volume of the prosthesis material is a function of the specific dimensions of the vertebral disc, the prosthesis volume may be gathered from CT scan data, MRI data or other similar data from another imaging protocol. Thus, for example, prostheses with lesser volume can be used with smaller discs and those with limited herniation and those that otherwise require less NP displacement to increase disc height or intradiscal pressure.

In one illustrative embodiment, the volume of prosthesis material 50 inserted into the interior region of the vertebral disc may range between approximately 0.1 ml and approximately 6 ml. Other suitable volume ranges, such as between approximately 1 ml and approximately 2 ml or between approximately 0.5 ml to approximately 2 ml, may be employed, as the present invention is not limited in this respect. The amount of prosthesis material 50 implanted depends upon a number of factors, including the amount of vertebral tissue, such as NP, lost through any herniation or degeneration and any increase in stiffness vertebral tissue, such as NP, as it is displaced with the prosthesis material. Further, the amount of prosthesis material inserted may depend upon the resulting augmentation volume of the vertebral disc desired.

Typical failure modes with existing vertebral disc implants may be caused by placing the implant directly between two opposing endplates where the implant functions to resist compression. In this respect, the mechanical properties of the prosthesis may create a stress concentration along the endplates and fracturing of the endplates may occur. Furthermore, placing the prosthesis against both endplates may interfere with fluid and nutrient transfer in and out of the vertebral disc. Thus, in one illustrative embodiment, as shown in FIGS.

also be employed. Other suitable combinations of positions for the prosthesis also may be employed to achieve other desired results.

Prosthesis **50** can be formed into any suitable shape. Prosthesis **50** may be cube-like, spherical, disc-like, ellipsoid, rhombohedral, cylindrical, kidney, wedge, planar, or amorphous in shape as shown in FIGS. 6A and 6B. Further, a single prosthesis or prosthesis formed from multiple sections or separate pieces may be employed. A plurality of prostheses also may be employed and may be formed as beads, as shown in FIG. 8, substantially straight and/or spiral rods, as shown in FIG. 9, geometric solids, irregular solids, sheets or any other suitable shape disclosed herein or otherwise formed. Of course, any suitable combination of the above mentioned or other shapes may be employed.

In another embodiment, the prosthesis **50** is shaped to resist being extruded from the interior region of the vertebral disc **15**. In one example, as shown in the illustrative embodiment of FIGS. 7A and 7B, the prosthesis **50** is sized to be larger than the access opening **60** formed in the vertebral disc **15** for inserting the prosthesis **50**. Alternatively, or in addition, the prosthesis may be formed as a wedge, as shown, with the larger end of the wedge facing the opening **60** such that any force tending to push the wedge out the access opening would cause the prosthesis to occlude the access opening, **60**. Of course, the prosthesis may be shaped such that any axial loads on the prosthesis would tend to cause the prosthesis to move away from the access opening. For example, a wedge-shaped prosthesis with the smaller end facing the opening **60** may respond to axial loads by tending to move away from the opening.

To aid in healing of the disc or otherwise provide therapy, the prosthesis may be impregnated, coated or otherwise deliver various therapeutic agents, such as drugs, time-release drugs, genetic vectors, naked genes or the like to renew growth, reduce pain, aid healing, or reduce infection. In one embodiment, a device distinct from the prosthesis may be delivered to the disc to provide one or more therapeutic agents. Agents that affect tissue growth (either promoting or inhibiting) may also be delivered separately or as part of the prosthesis.

The prosthesis may be formed of any suitable material, as embodiments of present

zenograft, or bioengineered. Where rigid materials are employed, the prosthesis may be shaped as small particles, powders, balls or spheres.

In some embodiments of the present invention, a multiphase system may be employed; for example, a combination of solids, fluids or gels may be used. Such materials may create primary and secondary levels of flexibility within an vertebral disc space. Thus, in use, the spine will flex easily at first as the vertebral disc pressure increases and the fluid flows, loading the annulus. Then, as the disc height decreases flexibility may decrease. This combination may also prevent damage to the AF under excessive loading as the prosthesis may be designed to resist further compression such that further pressure on the AF is limited.

Any of a variety of additional additives such as thickening agents, carriers, polymerization initiators or inhibitors may also be included, depending upon the desired infusion and long-term performance characteristics. In general, "fluid" is used herein to include any material which is sufficiently flowable at least during the infusion (i.e., implantation) process, to be infused by a delivery device into the interior region of the vertebral disc. The prosthesis material may remain "fluid" after the infusion step, or may polymerize, cure, or otherwise harden to a less flowable or nonflowable state.

In one embodiment, in situ polymerizing prosthesis materials that are well-known in the art and are described in U.S. Pat. No. 6,187,048, incorporated herein by reference, may be used. Phase changing augmentation preferably changes from a liquid to a solid or gel. Such materials may change phases in response to contact with air, increases or decreases in temperature, contact with biologic liquids or by the mixture of separate reactive constituents. These materials may be delivered through an opening in the AF or down a tube or cannula placed percutaneously into the disc. Once the materials have solidified or gelled, they may exhibit the previously described characteristics of a solid prosthesis material.

Additional additives and components of the prosthesis material are recited below. In general, the nature of the material may remain constant during the deployment and post-deployment stages or may change, from a first infusion state to a second, subsequent

during the day. In one embodiment, the prosthesis is formed of a material that may enable it to absorb approximately 50% to 100% of its volume. However, the present invention is not limited in this respect and other suitable prosthesis materials or characteristics of a prosthesis material may be employed to achieve other rehydration volumes. Rubber and polymeric materials may be used. In one embodiment, a hydrogel, such as PVA, PGA or PMMA, may be used.

In one embodiment, the prosthesis material has a swelling pressure between approximately 1 MN/m^2 and approximately 9 MN/m^2 for given volume range between approximately 0.1 mL to about 6.0 mL. This may have the advantage of allowing a smaller prosthesis to swell and fit into the irregularities within the natural NP until equilibrium pressure is achieved. Rubber and polymeric materials may be used. In one embodiment, a hydrogel, such as PVA, PGA or PMMA, may be used.

In one embodiment, the prosthesis material may be formed as a hydrogel having a compressive strength ranging between approximately 2.5 MN/m^2 and approximately 3.5 MN/m^2 (such as 2.5–2.7 MN/m^2, 2.7–2.9 MN/m^2, 2.9–3.1 MN/m^2, 3.1–3.3 MN/m^2, and 3.3–3.5 MN/m^2).In addition, the prosthesis material may preferably have a swelling characteristics that enables it to rehydrate approximately 50% to 100% (such as 50%-60%, 60%-70%, 70%-80%, 80%-90%, and 90-100%) of its volume. In one embodiment, this occurs within a 1 hour to 8 hour time period (such as 1-2 hours, 2-3 hours, 3-4 hours, 5-6 hours, 6-7 hours, 7-8 hours). One of skill in the art will understand that other time periods may also be used in accordance with embodiments of the present invention. In one embodiment, this occurs under a compressive stress ranging from approximately 0.2 MN/m^2 and approximately 0.8 MN/m^2 (such as 0.2-0.3 MN/m^2, 0.3-0.4 MN/m^2, 0.4-0.5 MN/m^2, 0.5-0.6 MN/m^2, 0.6-0.7 MN/m^2, 0.7-0.8 MN/m^2). Further, the prosthesis material may hydrate in less time when in an unloaded or unconstrained environment. Further, in this embodiment, the prosthesis material may have a Poisson's ratio ranging from approximately 0.35 to approximately 0.49 under a compressive stress ranging from approximately 0.5MN/m^2 to approximately 2 MN/m^2. Rubber and polymeric materials may be used. In one embodiment, a hydrogel, such as PVA, PGA or PMMA, may be used.

In some embodiments it may be desirable to provide a more uniform loading at the

In use, the pressurized disc tissue and prosthesis **50** applies force on the inwardly facing surface of the barrier **70**. This pressure may be exploited by the design of the barrier to reduce the likelihood of it dislodging or moving from its intended position. One exemplary barrier is shown in FIG. 11, where the barrier **70** includes inwardly facing surfaces **72** that expand upon the application of pressure. As the barrier expands, it becomes less likely to be expelled from the disc. The barrier **70** may be formed with a concavity facing inwardly to promote such expansion. In addition, as shown in FIG. 10, the prosthesis material **50** typically is positioned adjacent to the barrier **70** such that the likelihood of natural NP escaping through the access opening **60** is further minimized.

The barrier may be flexible in nature. It can be constructed of a woven material such as Dacron or Nylon, a synthetic polyamide or polyester, a polyethylene, or can be an expanded material, such as expanded polytetrafluroethylene (e-PTFF). The barrier may also be a biologic material such as cross-linked collagen or cellulous.

The barrier typically is a single piece of material, and may be expandable or include a component that allows it to be expanded from a compressed state after insertion into the interior of the disc. This expansion may be active, such as a balloon, or passive, such as a hydrophilic material. The expansion may also occur via a self-expanding deforming barrier or by incorporating such a material, such as a shape-memory material, for example. In the example shown in FIG. 11, the barrier **70** includes a cage **74** formed from a shape-memory material, such as nitinol. A cover (not shown) may be employed over the cage **74**.

When a phase changing prosthesis material is used, the barrier or other annulus augmentation may be permanently implanted or used only temporarily until the desired phase change has occurred. For example, a sufficient amount of fluid or liquid prosthesis **50** may be implanted into the disc. Barrier **70** is then implanted to occlude the access opening **60**. The prosthesis **50** is then cured or dried (or otherwise allowed to cure or dry) to a solid or semi-solid state, wherein the resulting prosthesis form is larger than the access opening. The barrier **70** then may be removed, as, due to the resulting size and/or shape of the prosthesis, the likelihood of the prosthesis escaping back through the access opening **60** is low.

herein may be supplied in a kit. The kit may include one or more of the same or different prostheses or components and/or one or more of the same or different deployment devices. The kit may include materials or devices to be used with the prosthesis. For example, the kit may include the above-mentioned therapeutic agents or agents to cure the prosthesis, if a curable prosthesis is employed. Also, the kit may include components, devices or other materials to aid in deploying the prosthesis. The kit further may include one or more of the same or different barriers. The kit also may include monitoring devices to monitor the amount of prosthesis being deployed and also may include instructional information, including any of the methodologies described herein. It should be appreciated that embodiments of the present invention are not limited in this respect, as the herein noted or other suitable components or devices may be supplied with the kit.

In some instances, it may be desirable to locate the prosthesis material within a certain position in the interior region of the vertebral disc. Thus, in one illustrative embodiment as shown in FIGS. **12A-12C**, the deployment device includes a depth stop **88** that limits how deeply into the interior region of the vertebral disc the prosthesis is placed. For example, the depth stop **88** may seat against the vertebral bodies **28**, **30**, as shown in FIG. 12C, or the AF **17**. In this manner, the tip **84** of the delivery device **80** is inserted into the access opening **60** in the AF until the depth stop **88** contacts the outer layer of the AF to prevent further insertion of the tip of the delivery device into the interior region of the vertebral disc. Once in this position, the delivery device is actuated to deliver the prosthesis **50** to the desired location. Although in this embodiment the depth stop **88** abuts the vertebral body to limit the insertion depth, the delivery device may be configured such that the depth stop abuts other anatomical features. For example, the depth stop may be located on a delivery device such that it is adapted to contact the AF or other bone or tissue located in the region.

In the embodiment shown in FIGS. **12A-12C**, the depth stop **88** is located on the outside of the delivery device. However, in other embodiments, an example of which is shown in FIG. 13, it may be desirable to configure the delivery device **80** with an internal depth stop **90**. In this manner, the tip of the delivery device is placed through the access opening in the AF and is advanced until the internal depth stop **90** contacts the opposite wall of the AF or other structure within the interior region of the vertebral disc. Once the tip is in the proper

One illustrative embodiment of an articulatable end is shown in FIG. 16. Guide wires **110** are fixed to the tip **84** of the delivery device, and in one embodiment, the guide wires **110** are anchored using suitable anchors, such as eyelets, in the interior region of the body **82**. The wires **110** extend internally through body **82** toward the proximal end **81** of the body **82** and exit end **81**. Retracting the wires **110** causes the tip **84** to articulate relative to the longitudinal axis of the delivery device. Other mechanisms for causing the tip to curve or bend may be employed. To provide for an articulating end, the distal end **84** is formed of a flexible material or in a flexible configuration.

In another embodiment, rather than actively deforming the tip of the delivery device, the tip itself may be configured such that it bends into a predetermined configuration upon insertion. For example, the tip of the delivery device may include a kink point or a change in the stiffness along the length of the tip that causes the tip to assume a predetermined configuration. In one embodiment, as shown in FIG. 17, the delivery device **80** includes a relatively stiff outer tubular member **112** that contains the body **82**. Further, body **82** may be formed of, or otherwise include, a relatively flexible material, such as a spring member, that holds the tip in a bent configuration. When inside the sleeve **112**, the tip is retained in a, straight configuration to allow insertion into the vertebral disc. When body **82** is displaced with respect to member **112** in the direction of arrow B, the tip **84** emerges from the sleeve **112** and assumes its bent configuration, as shown.

When a curved or otherwise articuatable end is employed, plunger **86** is, in one embodiment, sufficiently flexible to conform to the shape of the tip of the delivery device when in its bent configuration so as to be able to dislodge the prosthesis material.

In some circumstances, it may be desirable to place the prosthesis at a desired location within the interior region of the vertebral disc upon retracting a portion of the delivery device rather than by extruding the prosthesis material from the delivery device **80**, as in the embodiment shown in FIGS. 12A-12C. Thus, in this embodiment shown in FIGS. 18A-18C, and FIG. 19, a retrograde delivery device **80** is shown, wherein the body **82** is retracted in the direction of arrow C (see FIG. 18B) relative to the plunger **86**. Once the

shown, or other openings. Alternatively, as shown in FIG. 20B, the perforations may be in the form of fins **132'** that direct the liquid or fluid prosthesis material in the direction of arrow D'. In one embodiment, the delivery device includes perforations extending only radially outwardly. In this manner, direct pressure through the end of the delivery device onto the NP or locating the prosthesis in an otherwise undesirable location may be avoided.

In another embodiment, the deployment device monitors the amount of material being delivered. In one illustrative embodiment as shown in FIGS. **21A-21B** and **20**, the delivery device **80** includes a gauge **140** such that the surgeon, for example, may quickly determine the amount of prosthesis material being deployed from the delivery device. In one embodiment, the gauge **140** may be a pressure gauge that may be used to determine the increase in pressure within the vertebral disc as the prosthesis material is being deployed. In one embodiment as shown in FIG. 21A, the gauge may include a pressure sensitive transducer **142** disposed on or within the plunger **86** and suitable electronics (not shown) to record and measure the pressure within the disc. The pressure transducer may be situated on the delivery device such that it records the resistance to insertion force. The resistance force is correlated to the pressure increase within the vertebral disc such that the surgeon would know when enough prosthesis material has been deployed. The pressure also may be determined with the use of a suitably placed strain gauge.

Alternatively, the gauge may be a mechanical gauge **144** As shown in FIG. 21B, that employs a spring **146** and an indicator **148** coupled to the spring that moves in response to the resistance to insertion force. Again, the resistance force may be correlated to the increase in pressure in the interior region of the disc such that when a certain resistance force is obtained, further insertion of prosthesis material may be terminated. In this embodiment, the plunger **149** is formed as a two-part plunger having a first plunger **149**A and a second plunger **149**B. Spring **146** is disposed between the two plungers. Moving plunger **149**A causes spring **146** to compress and act on plunger **149**B, which in turn dislodges prosthesis **50**. As the resistance to insertion increases, plunger **149**A moves further into plunger **149**B and a higher pressure reading is indicated at indicator **148**. It should be appreciated that embodiments of the present invention are not limited to any particular gauge as any suitable gauge may be employed to determine the increase in pressure in the interior region of the vertebral disc.

At least one component prosthesis from the group, or the entire group, may be deployed to any desired location, examples of which are discussed above. In one embodiment, the grouping includes at least two components forming the prosthesis. In another embodiment, the grouping includes at least three components forming the prosthesis. Other suitable grouping sizes, such as four, five and six, may be employed, as the present invention is not limited in this respect. In one embodiment, the multi-component prosthesis can, for example, comprise hydrogel spheres, that can be extruded, ejected or otherwise dispensed from the delivery device, thereby displacing, without removing, autologous vertebral tissues. As is apparent from the above discussion, the size of the group may depend upon certain factors. For example, as is apparent from the above discussion, the group size may be a function of the desired disc height, the desired disc pressure or the desired disc volume, such as the desired augmentation volume.

FIG. 23A is a cross-sectional view of a delivery device **80** loaded with a grouping of spherical or bead shaped prosthetic components **50'** and with the plunger **86** in the retracted position. FIG. 23B shows the plunger **86** in the advanced position, with the components **50'** of the prosthesis deployed as a group from the distal tip **84**. FIG. 23C shows a view of two adjacent vertebral bodies **28, 30**, with the tip **84** of the delivery device **80** inserted within the vertebral disc. Depth stop **88** is placed against at least a portion of the annulus or vertebral body. The plunger **86** is shown in the advanced position in which the prosthesis **50'** has been delivered within the area bounded by the annulus, causing the tissues of the annulus, nucleus, or vertebral endplates to be displaced in relation to the amount of prosthesis added.

FIG. 24A is a cross-sectional view of a retrograde delivery device (such as that described above with respect to FIGS. **18A-18C**), which is loaded with rod- or spiral-shaped prosthetic components **50"** and with the body **82** advanced relative to the plunger **86**. FIG. 24B shows the body **82** in the retracted position relative to the plunger **86**, in which the components **50"** of the prosthesis are deployed as a grouping from the distal tip **84**. FIG. 24C shows a view of two adjacent vertebral bodies **28, 30**, with the tip **84** delivery device **80** inserted within the vertebral disc. Depth stop **88** is placed against at least a portion of the annulus or vertebral body. The body **82** of the delivery device is shown in the retracted position relative to the plunger **86**, with the prosthesis **50** delivered within the area

WHAT IS CLAIMED:

1. A prosthesis for implantation into an interior region of a vertebral disc, the prosthesis comprising:

an isotropic mass of biocompatible hydrogel, wherein said biocompatible hydrogel has a compressive strength, a volume, and a mass,

wherein said compressive strength is less than about 4 MN/m^2,

wherein said volume is in the range of between about 0.1 ml and about 6.0 ml, and,

wherein the mass of said hydrogel is adapted to absorb a volume of about 50% to about 100% of the volume of the hydrogel under a compressive stress between a range of about 0.2 MN/m^2 and about 0.8 MN/m^2

2. The prosthesis of Claim 1, wherein the mass of said hydrogel is adapted to absorb a volume of about 50% to about 100% of the volume of the hydrogel in a time period of about1 hour to about 8 hours.

3. A prosthesis for implantation into an interior region of a vertebral disc having first and second endplates, the prosthesis comprising:

a mass of material adapted for insertion into the interior region of the vertebral disc so as to displace existing vertebral tissue,

wherein the mass of material is sized so as to be spaced from both the first and second endplates when implanted into the interior region of the vertebral disc such that the mass of material is surrounded with nucleus pulposus within the interior region of the vertebral disc when implanted therein.

4. The prosthesis according to Claim 3, wherein the mass of material is wedge-shaped.

5. A vertebral disc prosthesis for displacing nucleus, annulus, or vertebral body endplate tissue of a vertebral disc, the prosthesis comprising:

a grouping of at least two discrete components, wherein the grouping is constructed and configured to be inserted together as a group into the interior region of a vertebral disc to displace at least a portion of the nucleus, annulus, or vertebral body endplate tissue.

16. The method of Claim 15, further comprising determining when a sufficient amount of the prosthesis material has been inserted into the interior region of the vertebral disc based on the monitored characteristic.

17. The method of Claim 15, wherein locating an access site comprises forming an opening in the annulus fibrosis of the vertebral disc.

18. The method of Claim 15, wherein locating an access site comprises locating a defect in the annulus fibrosis of the vertebral disc.

19. The method of Claim 15, wherein monitoring one or more characteristics of the vertebral disc comprises monitoring a disc height of the vertebral disc.

20. The method of Claim 15, wherein inserting the prosthesis material into the interior region of the vertebral disc comprises inserting an amount of prosthesis material into the interior region of the vertebral disc until a desired disc height is achieved.

21. The method of Claim 20, wherein inserting an amount of prosthesis material into the interior region of the vertebral disc until a desired disc height is achieved comprises inserting an amount of prosthesis material into the interior region of the vertebral disc until a height ranging between about 1 mm to about 10 mm is achieved.

22. The method according of Claim 15, wherein monitoring one or more characteristics of the prosthesis material comprises monitoring a volume of prosthesis material inserted into the interior region of the vertebral disc.

23. The method of Claim 15, wherein inserting the prosthesis material into the interior region of the vertebral disc comprises inserting about 0.1 ml to about 6 ml of the prosthesis material into the interior region of the vertebral disc.

24. The method of Claim 15, wherein monitoring one or more characteristics of the vertebral disc comprises monitoring a disc pressure of the vertebral disc.

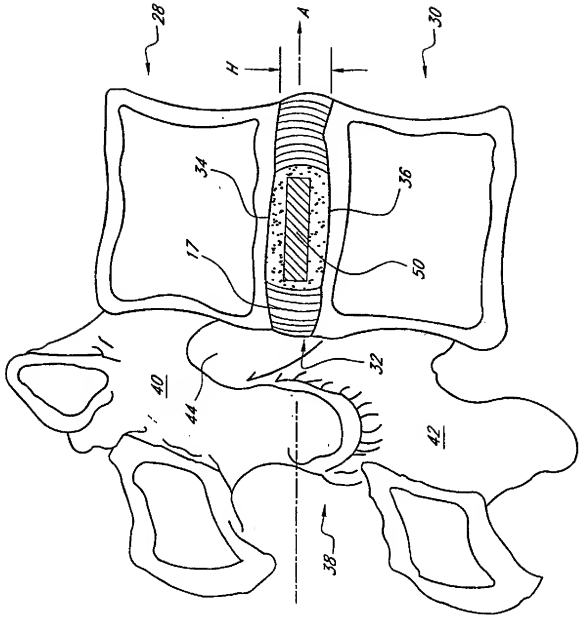


FIG. 1B

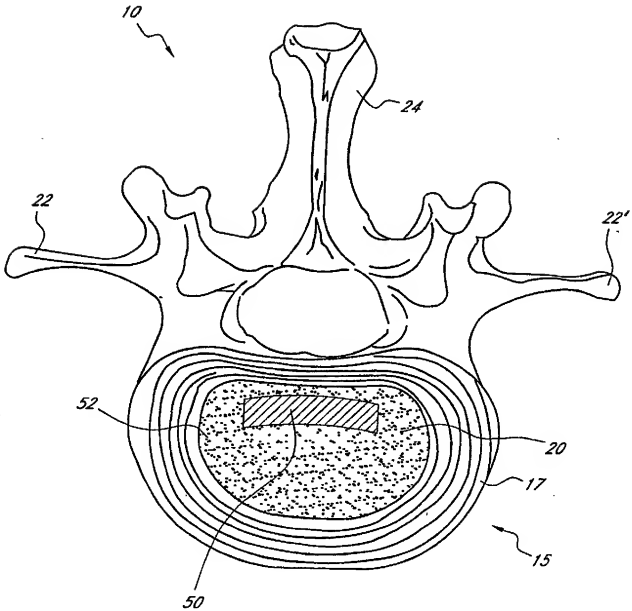


FIG. 3A

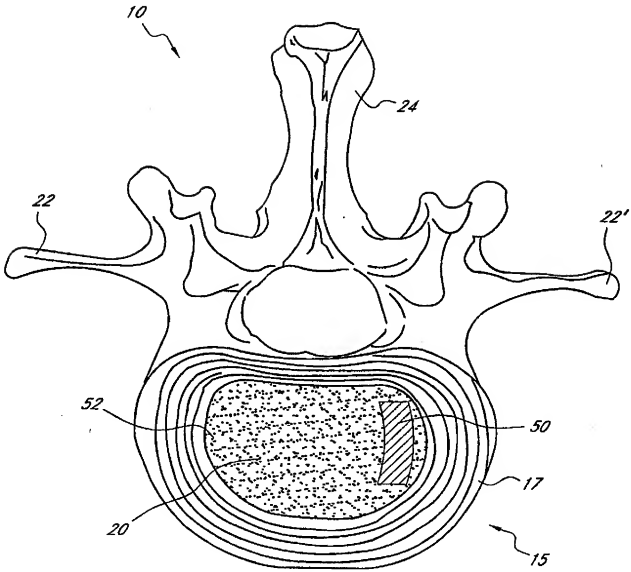


FIG. 4

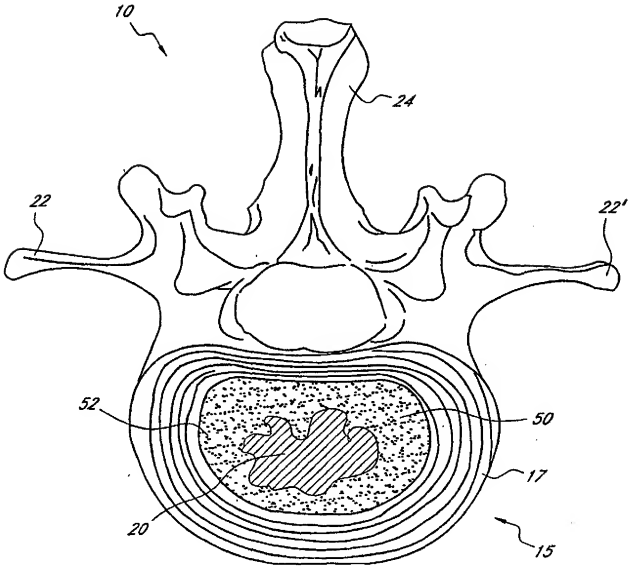


FIG. 6A

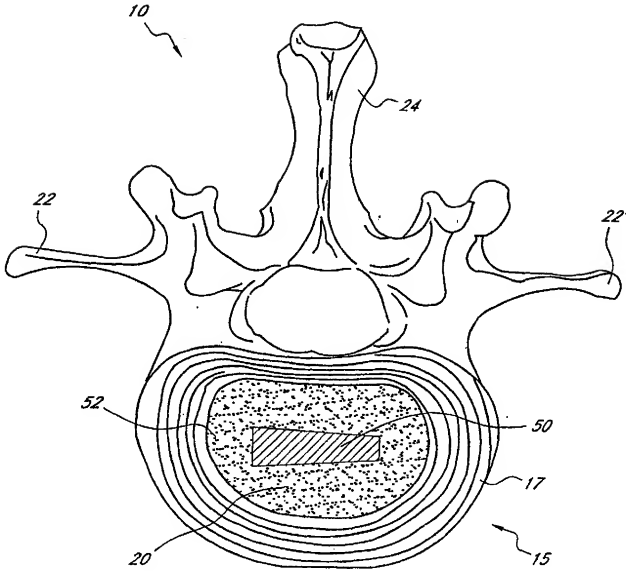


FIG. 7A

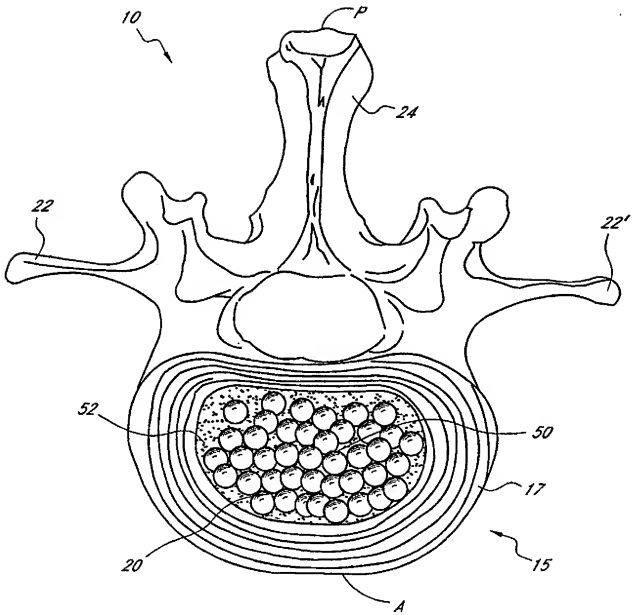


FIG. 8

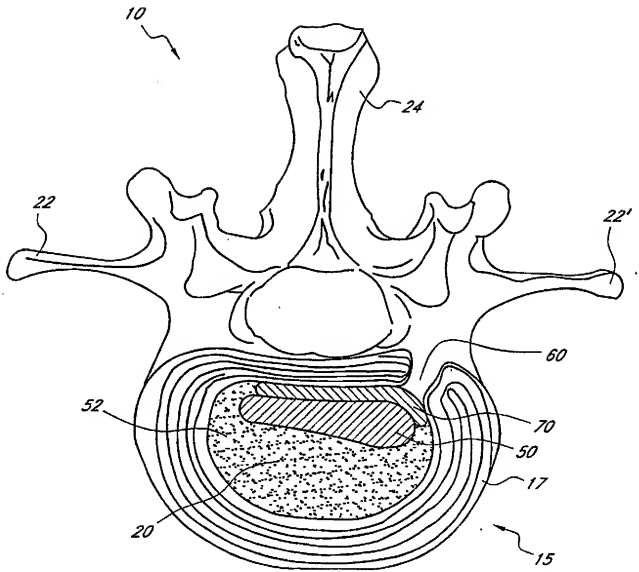


FIG. 10

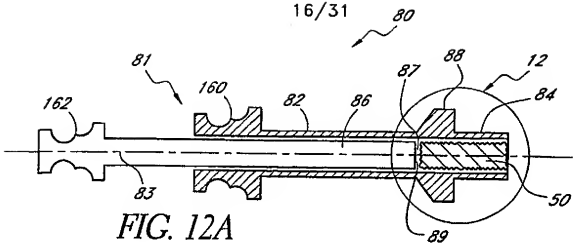


FIG. 12A

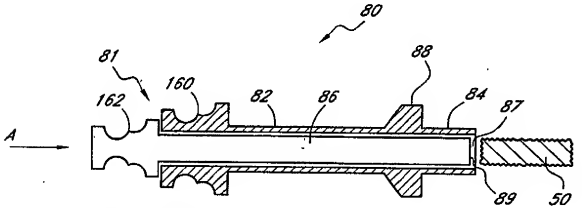


FIG. 12B

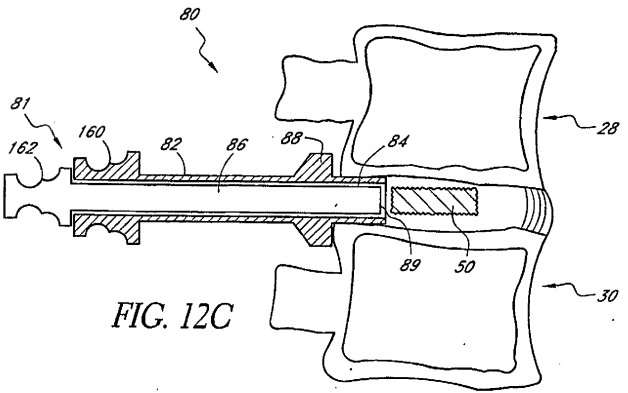


FIG. 12C

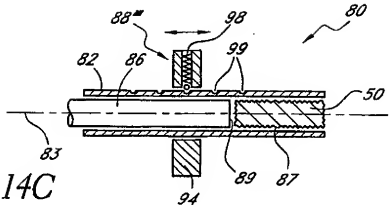


FIG. 14C

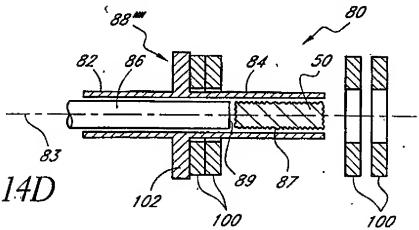


FIG. 14D

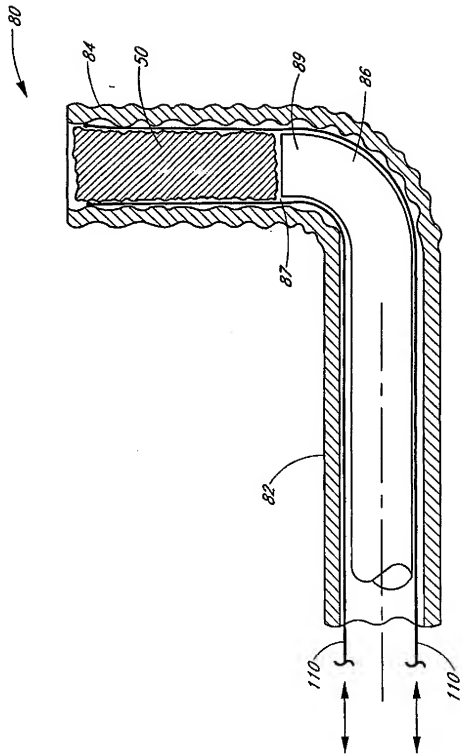


FIG. 16

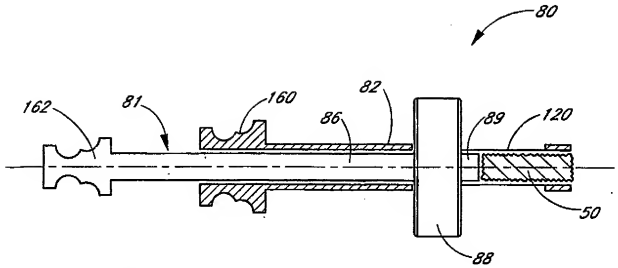


FIG. 18A

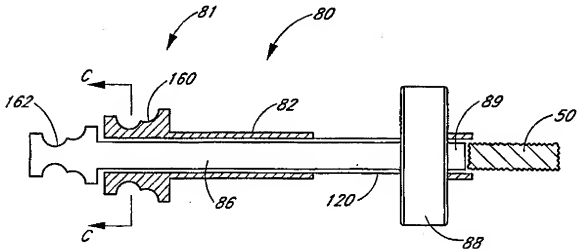


FIG. 18B

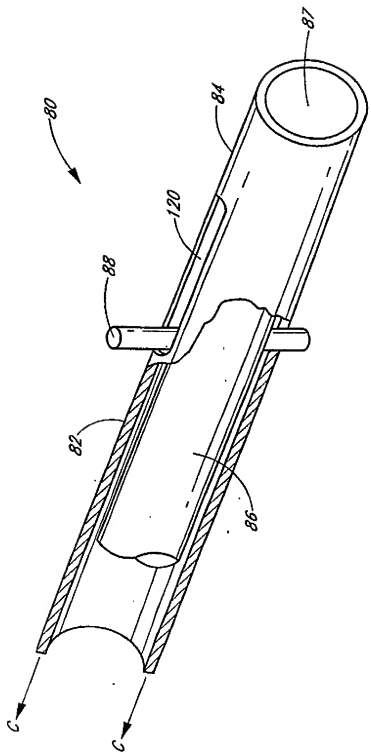


FIG. 19

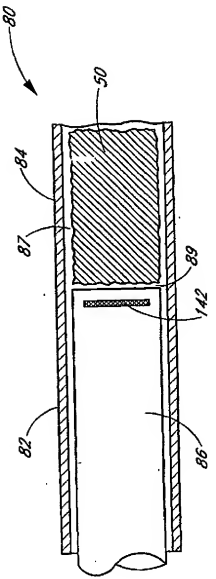


FIG. 21A

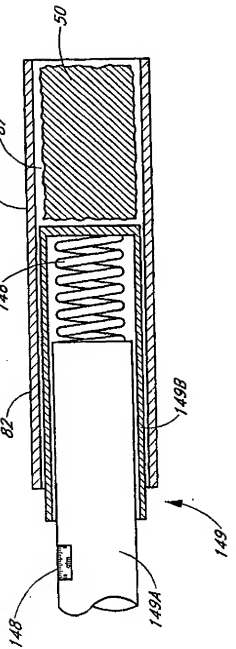


FIG. 21B

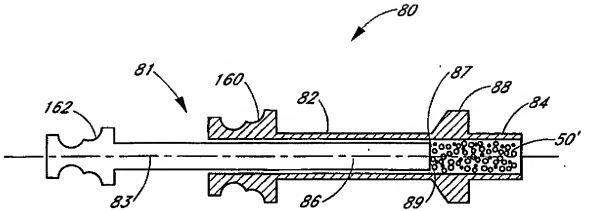


FIG. 23A

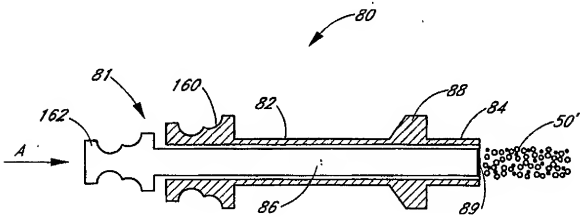


FIG. 23B

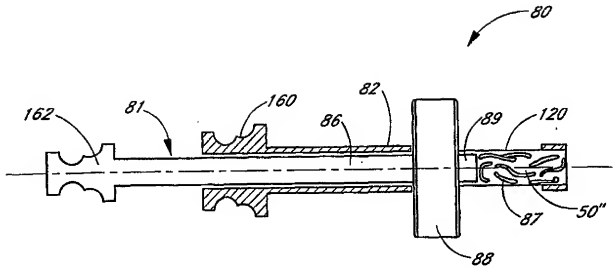


FIG. 24A

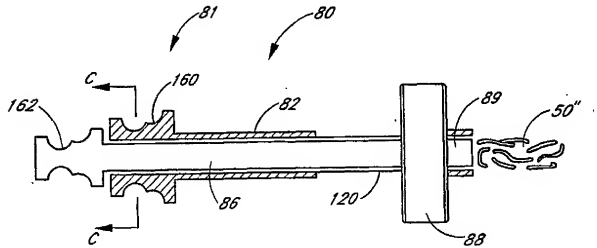


FIG. 24B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/14346

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 2/44
US CL : 623/17.12, 17.16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/17.12, 17.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,132,465 A (RAY et al) 17 October 2000 (17.10.2000), Fig. 8, column 6, line 29-column 19, line 50.	3-5, 7, 9-10, 15-24
X	US 6,264,695 B1 (STOY) 24 July 2001 (24.07.2001), column 4, line 39- column 18, line 11.	5-8,11-12,15
X --- Y	US 5,702,454 A (BAUMGARTNER) 30 December 1997 (30.12.1997), Fig. 1, column 2, lines 39-59.	5, 7, 14 --- 13
Y	US 5,047,055 A (BAO et al) 10 September 1991 (10.09.1991), column 6, lines 4-10.	13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
04 September 2004 (04.09.2004)

Date of mailing of the international search report
01 NOV 2004

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer
Thomas Barrett
Sheila H. Verley
Paralegal Specialist
Tech. Center 3700

Telephone No. 703 308 8295

Form PCT/ISA/210 (second sheet) (January 2004)